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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,675	02/16/2004	James Say	20786US01	7215

23446 7590 03/24/2010

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EXAMINER	
LAU, TUNG S	

ART UNIT	PAPER NUMBER
2863	

MAIL DATE	DELIVERY MODE
03/24/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,675	SAY ET AL.	
	Examiner	Art Unit	
	TUNG S. LAU	2863	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-148* is/are pending in the application.

4a) Of the above claim(s) *41-54,70-72 and 74-148* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55-69 and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. A response on 10/09/2008 a provisional election was made without traverse to prosecute the invention of claims 55-69 and 73. Claims 41-54, 70-72 and 74-148 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Because these inventions are distinct for the reasons given on action 06/18/2008, the restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 69, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Joseph Jeffrey (WO 97/01986, January 23, 1997).

Regarding claim 55:

Joseph Jeffrey describes a device for monitoring glucose concentration in a biological sample of a host (page8), the device comprising: a substantially continuous glucose sensor that produces a data stream indicative of a glucose concentration in a host (page 9) the data stream comprising a plurality of time spaced sensor data points (page 9); an integrated receiver that receives the data stream from the substantially continuous glucose sensor (page 9, 10, fig. 13), wherein the integrated receiver comprises: a single point glucose monitor (fig. 18a, unit 420) configured to receive a biological sample from the host and to measure the concentration of glucose in the sample (fig. 18a, 18c, unit 330), the measured glucose concentration (page 11) comprising a reference data point (page 35, 36); a processor (fig. 13A, unit 300); and a computer readable memory (fig. 13A, unit 300) comprising: instructions configured to cause the processor to process the data stream received from the continuous glucose sensor (page 35, fig. 13A, 300, 330); instructions configured to cause the processor to determine a rate of change of the data stream from the substantially continuous analyte sensor (fig. 13d); and instructions configured to cause the processor to calibrate the data stream (page 28) using the glucose concentration measured by the

single point glucose monitor (page 28, 31, 34, 35, 36 weekly calibration if needed using blood for glucose information, claim 24).

Regarding claim 56, Joseph Jeffrey further describes the reference input module is configured to reject a reference data point obtained when the rate of change of the data stream is above a threshold (page 35, noise removal algorithms).

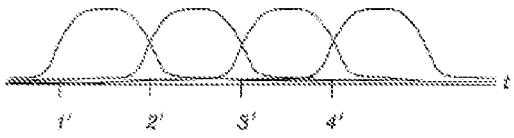


FIG. 13d

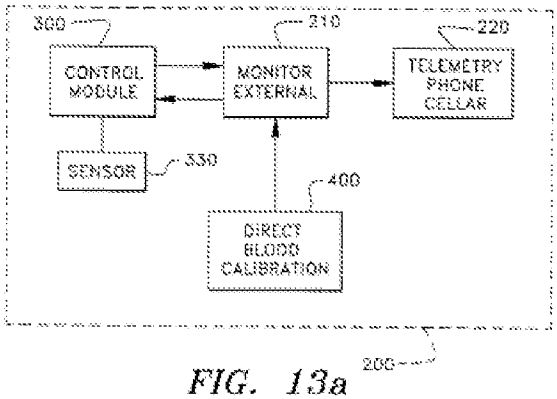


FIG. 13a

Regarding claim 57, Joseph Jeffrey further describes a data matching module configured to match a reference data point to a sensor data point to form a matched data pair (page 25, to calculate pulse wave velocity from sensor pair, page 35, multispectral correlation), wherein the reference data point and the sensor data point are obtained at substantially corresponding times (fig. 13d, 13b), and wherein the rate of change of the data stream is below a threshold at the time the sensor data point is obtained (page 35, noise removal algorithms, real data to be use).

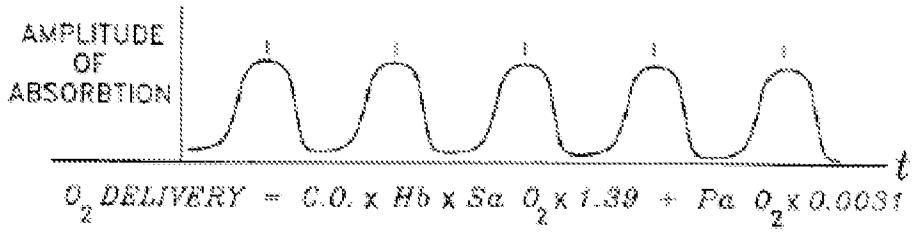


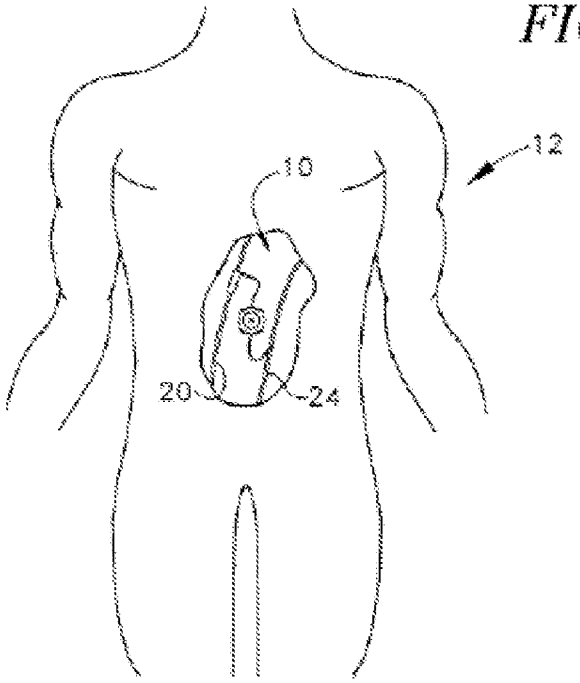
FIG. 13b

Regarding claim 58, Joseph Jeffrey further describes a calibration module (fig. 13a, unit 400) configured to form calibration information based at least in part on at least one reference data point and at least one sensor data point (page 28, 31, 34, 35, 36 weekly calibration if needed using blood for glucose information, claim 24), wherein the reference data point and the sensor data point are obtained at substantially corresponding times (fig. 13d, 13b), and wherein the rate of change of the data stream is below a threshold at the time the sensor data point is obtained (page 35, noise removal algorithms, real data to be use).

Regarding claim 59, Joseph Jeffrey further describes a conversion function module configured to create a conversion function based at least in part on at least one sensor data point (page 35, multispectral correlation), wherein the sensor data point is obtained when the rate of change of the data stream is below a threshold (page 35, noise removal algorithms, real data to be use), and wherein the conversion function is configured to convert the sensor data point into a calibrated data point (page 35, noise removal algorithms, real data to be use).

Regarding claim 60, Joseph Jeffrey further describes a sensor data transformation module (page 35, multispectral correlation) configured to convert at least one sensor data point into a calibrated data point (page 35, noise removal algorithms, real data to be use), wherein the rate of change of the data stream at the time at which the sensor data point is obtained is below a threshold (page 35, noise removal algorithms, real data to be use).

FIG. 1



Regarding claim 61, Joseph Jeffrey further describes a calibration module configured to form a calibration set based at least in part on at least one matched data pair (page 25, to calculate pulse wave velocity from sensor pair, page 35, multispectral correlation), the matched data pair comprising a reference data point and a sensor data point (page 35, noise removal algorithms, real data to be use), wherein the reference data point and the

sensor data point are obtained at substantially corresponding times (fig. 13b, 13d); and a calibration evaluation module configured to evaluate the matched pair (page 25, to calculate pulse wave velocity from sensor pair, page 35, multispectral correlation), wherein the calibration evaluation module is configured to prevent the matched data pair from influencing the calibration set if the rate of change of the data stream at the time the sensor data point is obtained is above a threshold (page 35, noise removal algorithms, real data to be use).

Regarding claim 62, Joseph Jeffrey further describes a clinical module (fig. 1, unit 10) configured to compare a first reference data point to a second reference data point to determine whether the first reference data point is clinically acceptable (page 35, noise removal algorithms, real data to be use), wherein the second reference data point is obtained prior to obtaining the first reference data point, and wherein the first reference data point is determined to be clinically acceptable if the difference between the first reference data point and the second reference data point is below a threshold (page 35, noise removal algorithms, real data to be use).

Regarding claim 63, Joseph Jeffrey further describes a clinical module (fig. 1, unit 10)configured to compare a first sensor data point to a second sensor data point to determine whether the first sensor data point is clinically acceptable (page 35, noise removal algorithms, real data to be use), wherein the second sensor data point is obtained prior to obtaining the first sensor data point (fig.

13b, 13d, signal are sequential in time to compare for noise), and wherein the first sensor data point is determined to be clinically acceptable if the difference between the first sensor data point and the second sensor data point is below a threshold (page 35, noise removal algorithms, real data to be use).

Regarding claim 64, Joseph Jeffrey further describes a stability module configured to determine whether the sensor data is stable (page 35, noise removal algorithms, digital bandpass), wherein the sensor data is determined to be stable if the rate of change of the data stream is below a threshold at the time the sensor data is obtained (page 35, noise removal algorithms, real data to be use).

Regarding claim 65, Joseph Jeffrey further describes the analyte comprises glucose (page 35), wherein the data stream comprises measurements indicative of in vivo glucose concentration (page 35), and wherein the threshold is set at a predetermined level (page 35).

Regarding claim 69, Joseph Jeffrey further describes a user interface (fig. 18A, 18b), wherein the user interface is configured to request additional reference data when the rate of change of the data stream is below a predetermined threshold (page 35, noise removal algorithms, real data to be use) .

Regarding claim 73, Joseph Jeffrey further describes a user interface (fig. 18A, 18b) configured to display (page 24) continuous glucose sensor data (fig. 13b, 13d) and single point glucose monitor data (fig. 18A, unit 420, 13b, 13d).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

a. Claims 66, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joseph Jeffrey (WO 97/01986, January 23, 1997) in view of B. Aussedat (A user-friendly method for calibrating a subcutaneous glucose sensor-based hypoglycaemic alarm, *Biosensors* & *Bioelectronics* Vol. *12. No.* I I, pp. 1061-1071, 1997, 1997 Elsevier Science Limited).

Regarding claim 66, Joseph Jeffrey further describes the analyte comprises glucose (page 35), wherein the data stream comprises measurements indicative of in vivo glucose concentration (page 10, 35),

Joseph Jeffrey does not describe the threshold is 0.25 mg/dL/min, B. Aussedat describes threshold can be calculate from any giving value (fig. 1) according to how one define the boundary and needs (fig. 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Joseph Jeffrey and B. Aussedat to have the threshold is 0.25 mg/dL/min in order to be more flexible according to one needs and the matter of design choice (In re Ieshin,125 USPQ 416).

Regarding claim 67, Joseph Jeffrey further describes wherein the analyte comprises glucose (page 10, 35), wherein the data stream comprises measurements indicative of in vivo glucose concentration (page 10, 35), Joseph Jeffrey does not describe the threshold is 0.5 mg/dL/min, B. Aussedat describes threshold can be calculate from any giving value (fig. 1) according to how one define the boundary and needs (fig. 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Joseph Jeffrey and B. Aussedat to have the threshold is 0.5 mg/dL/min in order to be more flexible according to one needs and the matter of design choice (In re Ieshin,125 USPQ 416).

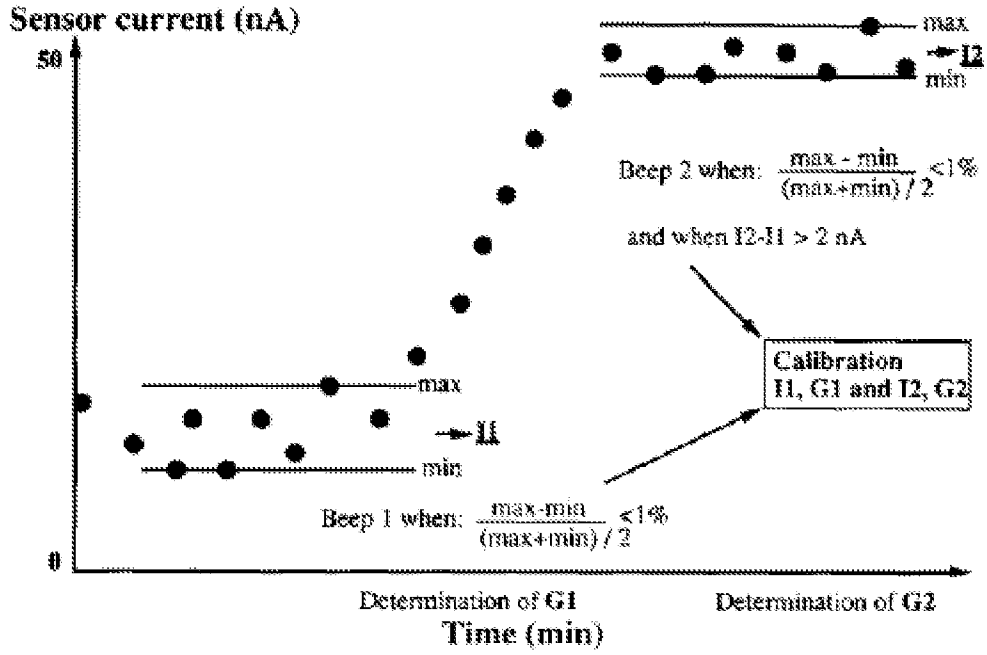


Fig. 1. Principle of the plateaus recognition performed by the ECU.

Regarding claim 68, Joseph Jeffrey further describes wherein the analyte comprises glucose (page 10, 35), wherein the data stream comprises measurements indicative of in vivo glucose concentration (page 10, 35), Joseph Jeffrey does not describe the threshold is greater than 0.5 mg/dL/min, B. Aussedat describes threshold can be calculate from any giving value (fig. 1) according to how one define the boundary and needs (fig. 1).
It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Joseph Jeffrey and B. Aussedat to have the threshold is greater than 0.5 mg/dL/min in order to be more flexible according to one needs and the matter of design choice (In re Ieshin,125 USPQ 416).

35 U.S.C. 103 authorizes a rejection where, to meet the claim, it is necessary to modify a single reference or to combine it with one or more other references. After indicating that the rejection is under 35 U.S.C. 103 (in light of KSR v. Teleflex, See MPEP 706.02(j)), the examiner should set forth in the Office action:

1. the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,
2. the difference or differences in the claim over the applied reference(s),
3. the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and
4. an explanation >as to< why >the claimed invention would have been obvious to< one of ordinary skill in the art at the time the invention was made.

Joseph Jeffrey and B. Aussedat are analogous art because they are from the same field of endeavor, glucose monitor device. (MPEP 706.02(j))

Response to Arguments

4. Applicant's arguments filed 06/04/2009 have been fully considered but they are not persuasive.

A. Applicant argues in the arguments that the prior art does not show in claim 55

1) a receiver comprising the combination of a single point glucose monitor and a processor with instructions to calibrate a data stream or (2) computer readable memory containing instructions configured to cause a processor to determine a rate of change of a data stream from a glucose sensor.

The examiner notice the argument is not exactly what being claim, what being claimed in claim 55 is:

Joseph Jeffrey describes a device for monitoring glucose concentration in a biological sample of a host (page8), the device comprising: a substantially continuous glucose sensor that produces a data stream indicative of a glucose concentration in a host (page 9) the data stream comprising a plurality of time spaced sensor data points (page 9); an integrated receiver that receives the data stream from the substantially continuous glucose sensor (page 9, 10, fig. 13), wherein the integrated receiver comprises: a single point glucose monitor (fig. 18a, unit 420) configured to receive a biological sample from the host and to

measure the concentration of glucose in the sample (fig. 18a, 18c, unit 330), the measured glucose concentration (page 11) comprising a reference data point (page 35, 36); a processor (fig. 13A, unit 300); and a computer readable memory (fig. 13A, unit 300) comprising: instructions configured to cause the processor to process the data stream received from the continuous glucose sensor (page 35, fig. 13A, 300, 330); instructions configured to cause the processor to determine a rate of change of the data stream from the substantially continuous analyte sensor (fig. 13d); and instructions configured to cause the processor to calibrate the data stream (page 28) using the glucose concentration measured by the single point glucose monitor (page 28, 31, 34, 35, 36 weekly calibration if needed using blood for glucose information, claim 24).

Reminds the applicant that Limitations appearing in the specification but not recited in the claim are not read into the claim. E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003).

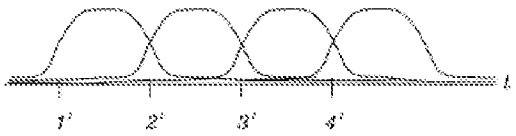


FIG. 13d

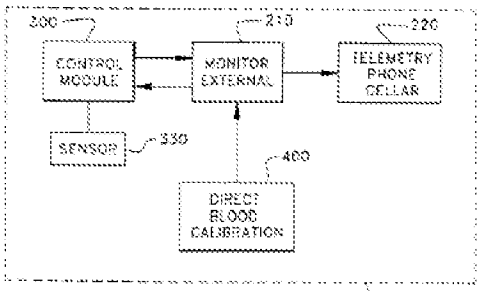


FIG. 13a

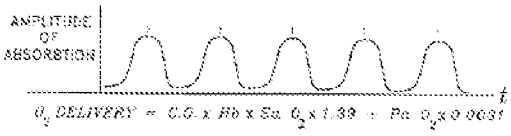


FIG. 13b

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact information

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tung S. Lau whose telephone number is 571-272-2274. The examiner can normally be reached on M-F 9-5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Drew Dunn can be reached on 571-272-2312. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Tung S. Lau/
Primary Examiner, Art Unit 2863
March 19, 2010